REMARKS

This is in response to the outstanding Official Action of August 11, 2008. Applicants request reconsideration and withdrawal of all outstanding rejections in favor of a Notice of Allowance for at least the following reasons.

The claims have been amended to more particularly point out and distinctly claim what applicants believe to be their invention. No new matter is added.

Claim 245 has been amended to more clearly recite that <u>both</u> the exterior wall and the interior liner are compliant, flexible materials capable of moving with the heart tissue as it undergoes dynamic expansion and contraction throughout systolic and diastolic actuation without causing abrasion of the epicardial surface of the heart. This is supported in the specification, e.g., at p. 23, l. 12-27; p. 103, l. 4-9; p. 103, l. 28- p. 4, l. 32; and p. 102, l. 18-29.

Claim 245 has also been modified to recite that the cup conforms to and seals with the surface of the heart from atrio-ventricular groove to apex, and the seating of the heart within the cup and the seal is maintained by imposing negative pressure between the interior or the cup and the heart, e.g., at the apex as shown in the various Figures. This is supported throughout the specification, e.g., p. 3; p. 86; p. 62, l. 7-16; p. 63, l. 7-17; and p. 73, l. 14-20. Such feature permits the retention of the heart within the device without the need for straps, sutures, clips or other means.

Claim 245 now recites that the method involves connecting the patient to a device that actively supports both systolic and diastolic actuation. This distinguishes over various references describing devices that provide only positive pressure, systolic support of the heart, but no diastolic support (i.e., the heart restores the device to its former shape or the elimination of positive pressure eliminates contact

between cup and heart). Support for this feature is found throughout the specification, e.g., at p. 9, l. 1-20; p. 30, l. 19-27; p. 45, l. 21-31; and p. 52, l. 13-26.

Other advantages of the method of the present invention, include added facility in manufacturing the device of the present invention. For example, with the designs and features of the present invention, as disclosed in the specification, the cup of the instant device can be made of substantially the same material throughout the cup. Thus, by selecting appropriate materials, and manufacturing those materials to appropriate specifications (e.g., thickness), one can make a cup that has the desired compliant flexibility such that the cup as a whole can be collapsed for less traumatic insertion while nonetheless producing a cup wherein the exterior wall supports the heart on diastolic actuation. This will facilitate various manufacturing efficiencies as where the cup is manufactured of a single piece. Support for unitary construction, use and selection of strain-neutral materials, and thickness of such materials (new claims 257-260) is found in the specification, e.g., at pp. 102-103 and 105.

Claim 245, and various dependent claims also recites the use of a transition section in the liner proximate the point of attachment with the wall that is tapered in thickness. This transition section reduces strain fatigue in the liner material, and promotes longevity of the device. Support is found in the specification at pp. 106, and Figs. 17B-C. That the transition section is configured to mate within a recess in, and be joined to, the wall is illustrated in Figs. 17C-D. One skilled in the art will appreciate that variations in the recess and mating structure of those two features are contemplated and readily implemented.

New claim 265, and various dependent claims, recite a similar method that, among other things, recites connecting the patient to a device having a rolling diaphragm liner. As explained within the specification, such a rolling diaphragm liner affords substantial additional carry and/or flexibility in the liner, which permits the liner to more freely move with the three dimensional motion of the heart as it goes through systolic and diastolic actuation. This greater range of motion affords several advantages, including a reduction in friction and/or abrasion between the interior liner and the epicardial surface of the heart. The rolling diaphragm is described thoroughly in the specification, including at pp. 65-67, and 103-107, and at Figs. 4A-4C, and 16-17. The rolling diaphragm can also be configured such that its normal motion automatically removes fluid seeping into the cup (e.g., self-bailing).

Prior Art Rejections

The claims stand rejected over Tsitlik in view of Kung. To the extent that Tsitlik discloses any method of treating a patient requiring heart function assistance and/or therapy, Tsitlik does so with a fundamentally different device. As such, Tsitlik neither teaches nor suggests the presently claimed invention.

Under the current election, applicants' claimed invention is a method of treatment comprising the use of a system for assisting pump function of a heart. The system includes, among other things, a cup. The cup includes an extrerior wall and an interior liner. Both are compliant. This feature affords several advantages.

First, the entire cup can be deformed or collapsed to facilitate installation of the device over the heart with minimal surgical intervention and thus reduced

trauma. The device can thus be installed in a variety of settings, including in the field.

Second, the compliant nature of the entire cup facilitates greater range of movement of the cup in three dimensions. The greater range of movement enables the cup to more effectively conform to and move with the heart, thus reducing abrasion between liner and heart tissue. Those skilled in the art will appreciate that the pumping of the heart is not merely a two-dimensional, linear pumping action, but rather one where the heart twists and contracts. The heart thus moves in three dimensions in a non-linear fashion.

By resort to a combined compliant outer shell and a compliant interior liner, the whole cup is capable of movement generally consistent with that of the heart. Thus, the interior liner does not bear the full burden of requisite elasticity and/or travel to avoid abrasion of the surface of the heart.

Additionally, the compliant nature of the exterior wall of the devices of the present method reduces reliance on elasticity and/or isotropic properties of the liner. This facilitates resort to a wider range of liner material and construction (e.g., thinner layers).

As now claimed, in certain embodiments the compliant capacity of the cup and liner are further extended by the incorporation of a rolling diaphragm liner. The rolling diaphragm may be introduced in the liner by configuring the point of attachment or the seams connecting the exterior wall and interior liner. *See, e.g.*, Figs 4A-4B. As can be seen from the various Figures, and as described throughout the specification, there is an upper seam connecting the exterior wall and the interior liner situated in the cup along a circumferential line generally corresponding to the

cup's contact with the atrio-ventricular groove; and there is a lower seam along a circumferential line about the apical region of the heart. The two seams thus form a continuous annular cavity between exterior wall and interior liner that can be displaced both positively and negatively to effect systolic and diastolic actuation of the heart.

The cup encompasses, and seals to and conforms to the surface of the heart from the atrio-ventricular groove to the apex. The seal between the cup and the heart at the atrio-ventricular groove facilitates a wider seal between the interior liner and the epicardial surface of the heart from the imposition and/or maintenance of negative pressure between the cup and the apical region of the heart. The negative pressure in combination with the A-V seal effects a vacuum seal over the heart, thereby maintaining the connection between cup and heart throughout systolic and diastolic actuation, and preventing ejection of all or a portion of the heart during positive pressure systolic actuation.

Another significant advantage of the instant invention is the combined use of the disclosed cup with: 1) sensors, 2) a control system, and 3) algorithms. This combined system achieves reliable installation of the cup, and more effective and predictable control of heart function.

As discussed, one objective in using a compliant cup (compliant liner and shell) is facile, atraumatic installation of the cup through relatively small incisions. While such minimally invasive installation is less traumatic to the patient, the physician is without visual guidance as to the location, fit, or function of the cup relative to the heart. This is especially significant where treatment is administered to a failing, rather than failed, heart, and the device must synchronize with a pumping

heart. For this reason, prior art cups emphasized the need for transparent, or at least translucent, materials in both the outer shell and interior liner. *See, e.g.*, Anstadt, USPN 5,119,804, col 5, lines 2-20 (preferring glass outer shells for rigidity and translucence).

The system of the instant invention is more versatile than the cups of the prior art. With its sensors, control system, and detailed algorithms, there is little need for visual guidance. The sensors detect various operational parameters, and feed corresponding data to a control system. The control system assesses the data according to one or more algorithms, and provides information as to proper installation of the cup, and directs synchronized fluid flow into the annular cavity of the cup to effect displacement of the liner and thereby effect (or assist) systolic or diastolic actuation of the heart consistent with the heart's natural rhythm. *See, e.g.*, Specification, p. 10.

The versatility of the claimed method is substantially related to the algorithmic control. The sensors, control system, and algorithms produce instantaneous detection, feedback, and adjustment of the device. Thus, the heart and device are consistently synchronous. Applicants addressed some of the advantages of such algorithmic control in a complex physiological environment in the specification.

> Functional interactions between the right ventricle and left ventricle under mechanical systolic and diastolic actuation are relatively complex and difficult to describe and/or characterize. These are dynamic interactions that are not necessarily predictable based on pre-measured variables, but rather depend on many physiologic variables. These interactions are not independent; thus the behavior of one chamber can have an effect on the other. Continuous monitoring of these two chambers allows the drive control to utilize an adaptive algorithm to constantly alter DMVA control parameters to achieve optimal cardiac actuation and hemodynamic output. Examples of this include, but are not limited to, adjustment of pressure/volume relationships to maintain balanced RV/LV output, control of pressure

> rise times to avoid herniation of the right ventricle, and reduction of negative drive pressure during diastole based on loss of contact between the DMVA liner and the heart wall.

Specification, p. 10, l. 8-18.

Further, automation of cup actuation minimizes reliance on operator expertise. By using the method and device of the present invention, less medical skill is required, and medical technicians of relatively modest training can use the device reliably and effectively in the field and/or at the scene of injury, and thereby more immediately administer life-saving therapy. It will be appreciated that, in most instances where this form of therapy is required, time is of the essence, and moments can make the difference between life and death. Thus, the ability to immediately install and implement the device is of substantial advantage, and will have profound public health benefits.

Tsitlik

Tsitlik purportedly discloses a heart assist device that is described as containing a housing having a cylindrical wall and an end wall. There is also said to be a fluid-impermeable flexible barrier membrane. There is sufficient barrier material "to permit the barrier material to reach the heart during the systolic phase without causing the material to be stretched." Col. 5, lines 5-20. Thus, the barrier material must be folded or gathered to afford excess material such that the barrier material maintains contact with the heart as it recedes from the wall of the device on systole. *E.g.*, col. 10, lines 44-53.

It can be readily seen from the various Figures and the description that the housing of Tsitlik is a rigid structure having various rigid, inelastic parts and connections. As such, the housing or "outer shell" of Tsitlik, to the extent there is

one, is not compliant. The inelastic cylindrical wall of the housing also puts greater demands on the barrier material, which must be configured to afford sufficient slack to maintain contact with the heart throughout compression.

Additionally, one skilled in the art would appreciate that the Tsitlik device does not provide affirmative diastolic actuation of the heart. Rather, there is described only a positive pressure pump assist function. *See, e.g.*, col. 7, lines 28-36 ("Once the systolic phase is complete, the fluid pressure transmitted through port 40 is reduced in a controlled manner to initiate the diastolic phase, as is well known in the art. When the predetermined minimum pressure is reached within chamber 36, *at which time no pressure is applied to the exterior of the ventricular walls* of the heart, barrier 22 may still conform to the exterior shape of the heart, or if the negative pressure is low enough, barrier 22 may withdraw to the interior walls of cylindrical wall 14." emphasis added); *see also* col. 10, lines 26-45. That there is a substantial period when no pressure is applied (either positive or negative), and as the barrier is said to withdraw to the interior walls of the housing, one skilled in the art would readily appreciate that Tsitlik's barrier is not engaged with the ventricular surface of the heart to effect (or assist) diastole.

In contrast, the instant specification discloses that the liner of the cup is substantially uniformly in contact with the surface of the heart throughout systolic and diastolic actuation. Such uniform contact is essential if effective affirmative diastolic actuation is to be achieved. *See, e.g.*, Specification, p. 22 (describing optimal diastolic actuation, wherein "diastolic actuation is adjusted to that point where maximal $-dP/dt$ is achieved without allowing separation between the actuating diaphragm and epicardial surface of the heart."). In this way, the seal that exists

between the liner and the heart surface is employed to effect active diastolic actuation.

The instant specification makes clear throughout that the device recited in the method of the instant claims actively engages the heart to effect (or assist) diastolic actuation. *See, e.g.*, p. 18, l. 30-32; and p. 22, l. 9-17. Tsitlik fails to teach how or why one might effectuate such diastolic assist or actuation.

The claims now recite a method involving a command instruction effecting displacement in the annular cavity, and "wherein said displacement actively supports systolic and diastolic actuation of the heart." The claimed device thus actively supports both biventricular compression ("systolic actuation") and active biventricular dilatation ("diastolic actuation"). Active support of both phases is an affirmative limitation of the independent claims, i.e., 245 and 265. It distinguishes prior art devices, particularly the direct cardiac compression ("DCC") devices. *See, e.g.*, Specification at pp. 1-3, & 9.

In Tsitlik, however, the liner is at best passively engaged with the surface of the heart by virtue of the positive pressure within the chamber. When that pressure is removed, Tsitlik's liner falls away from the heart. In Tsitlik, there is no active support of diastolic actuation. Additionally, Tsitlik teaches that the liner must be gathered or folded to afford the carry in the liner material needed to maintain contact with the heart throughout systole. Such a feature would frustrate, and thus teach away from, the maintenance of a seal between heart and liner. Thus, the Tsitlik apparatus is analogous to a DCC device, and does not teach or suggest the claimed invention.

Kung

Kung does not cure the deficiencies of Tsitlik. Kung purportedly describes a flow-balanced cardiac wrap. Kung describes a cuff or wrap that does not have a continuous annular cavity. Kung's cuff is an enclosed inflatable substantially cubic chamber, or a series of inflatable cubic chambers oriented along the cuff. The cuff is to be wrapped around the heart.

One of skill in the art would have understood that applicants' phrase "continuous annular cavity" refers to a cavity in which fluid can travel an annular path continuously. The continuous cavity affords the advantage of rapid, uniform pressure (positive and negative) on the heart. Kung does not afford or suggest that feature. Rather, in Kung, fluid flows unidirectionally into the chamber, and the fluid flow within the chamber is circumscribed by the shape, size and contours of the cuff. Indeed, Kung teaches away from the claimed invention by asserting that there are advantages to cuff configurations that impose differential pressure on the various regions of the heart.

In Kung the fluid pressurizing the cuff cannot circumnavigate the heart continuously to rapidly achieve uniform pressure throughout the chamber as in the claimed cup. Thus, Kung does not teach or suggest a device having a continuous annular cavity surrounding the ventricles of the heart.

Further, Kung does not teach or suggest a device providing displacement within the continuous annular cavity that "actively supports systolic and diastolic actuation of the heart." The Kung device is analogous to a DCC device wherein positive displacement within the various chambers of the cuff assists in the systolic actuation of the heart; but there is nothing teaching or suggesting that the device has

any capacity whatsoever for actively supporting the diastolic actuation of the heart. Indeed, one of skill in the art reading Kung would immediately understand that the device does not support diastolic actuation. Thus, neither Tsitlik nor Kung, alone or in combination, teach or suggest a device capable of actively supporting both systolic and diastolic actuation.

Among other things, the instant invention further distinguishes over Kung, and its various controls and sensors, by claiming embodiments requiring that the device comprise a sensor that detects the maintenance of negative pressure, and the fit of the cup over the heart. The instant method involves use of a cup installed and maintained over the heart by negative pressure (*e.g.*, through line 160). Claimed embodiments include a sensor that can monitor maintenance of negative pressure, and hence confirm that the heart is properly seated within the cup, and that there is an effective seal between liner and heart. If negative pressure is not maintained, particularly at the apical region of the heart, then the cup and the heart are no longer in a suitable functional relationship, and the cup will not be efficiently assisting the heart, particularly during diastole.

Kung does not teach or suggest this aspect of the invention as Kung is a fundamentally different structure. Kung teaches that its device is affixed to the heart by mechanical means, e.g., microhooks or sutures. *E.g.*, Col. 6, l. 23-31. Those mechanical attachment means are designed to grip the heart, and prevent its ejection from the cup in response to the positive pressure imposed on the heart during systolic actuation. As Kung does not teach or suggest imposing a negative pressure between its device and the surface of the heart, one skilled in the art would not have been motivated by Kung to include a sensor for monitoring such parameter.

Accordingly, Kung likewise fails to teach or suggest this aspect of the claimed invention. For at least the foregoing reasons, Kung fails to teach or suggest, alone or in combination with Tsitlik, a device having sensors to monitor the pressure between cup and heart, and the claimed invention is neither taught nor suggested by Tsitlik and/or Kung.

CONCLUSION

In view of the foregoing amendments and remarks, applicants respectfully request reconsideration and withdrawal of all outstanding rejections. Applicants submit that the claims are now in condition for allowance, and respectfully request formal notification to that effect. If, however, the Examiner perceives any impediments to such a notice of allowability, whether substantive or formal, the Examiner is encouraged to call Applicants' attorney at the number provided below. Such informal communication will expedite examination and disposition of this case.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: September 11, 2008

By:

Brian P. O'Shaughnessy
Registration No. 32747

P.O. Box 1404
Alexandria, VA 22313-1404
703 836 6620